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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/742,785 | 12/20/2000 | William J. Curatolo | PC10755AJTJ | 8464 |

7590 02/08/2005
Gregg C. Benson
Pfizer Inc.
Patent Department, MS 4159
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EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/742,785

Applicant(s)

CURATOLO ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>01/24/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1-15,18-44,47-72,75-92,95-102,104-112,115-122,124-132 and 135-163.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 3-11,19-24,32-40,48-53,60-68,76-81,88-91,96-101,108-111,116-121,128-131,136-141 and 148-150.

Continuation of Disposition of Claims: Claims rejected are 1,2,12-15,18,25-31,41-44,47,54-59,69-72,75,82-87,92,95,102,104,107,112,115,122,124-127,132,135,142-147 and 151-163.

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DETAILED ACTION

Examiner acknowledges receipt of IDS, amendment, remarks and request for continued examination under 37 CFR 1.114, all filed 01/24/05. Claims 1-15,18-44,47-72,75-92,95-102,104-112,115-122,124-132 and 135-163 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 01/24/05 has been entered.

Claim Rejections - 35 USC § 112

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 146, 147, 151-155, 162 and 163 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Part (c) of claim 146 and part (d) of claim 155 are confusing. Claim 146 is examined as an aqueous solution that contains a drug and concentration enhancing polymer, where at least a portion of the drug in solution is associated with at least a portion of the polymer to form drug-polymer particles having a size of from about 10 nanometers to about 1000 nanometers; and the concentration of the drug in the solution is at least 1.25-fold the equilibrium concentration of said drug.

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Applicants argue that claims 146 and 155 are composition claim and the how the solution is made is not critical. Applicants further state that Examiner provided no factual basis for holding the claims unclear.

Examiner agrees with applicants that in a product by process claim, the manipulations of the recited steps are not critical, only the structure implied by the steps are critical. While determination of patentability is based on the product itself, the claims as a whole have to be clear and not confusing. Examiner respectfully asks the applicants to please look at claims 146 and 155, with emphasis on parts (c) and (d) and the claims in general.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 1, 2, 12-15, 18, 25-31, 41-44, 47, 54-59, 69-72, 75, 82-87, 92, 95, 102, 104-107, 112, 115, 122, 124-127, 132, 135, 142-145 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al. (US 5,496,561).

Okada is relevant to the examined claims and the previous rejection applies here.

Applicants emphatically traverse the rejection of the claims as being anticipated by Okada on the grounds that Okada does not describe a composition that comprises solubility improved form of a drug and one of the cellulose polymers required by the claims. Applicants further state; “the fact that some of the individual elements (e.g., drugs generally and some of Applicants’ polymers) disclosed randomly in Okada might be appropriately combined with applicants disclosure is insufficient to support the rejection because there is no written description or enablement in Okada of Applicants’

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invention.” In summary applicants traverse Okada by stating that Okada does not disclose the instant composition and that the composition as amended require a physical mixture of the drug and the polymer, which applicants say is not disclosed by Okada.

6. Applicants' arguments filed 01/24/2005 have been fully considered but they are not persuasive.

The generic claims are directed to a composition that comprises a drug in a solubility improved form, a concentration enhancing polymer and the composition is not a dispersion and the claims further limit the polymers to that recited. It is respectfully noted that the composition requires one of the polymers recited and not all of the polymers recited. Claim 2 directs the solubility-improved drug to be a crystalline drug. The Okada reference is not combined with applicants disclosure, rather Okada discloses the composition.

Okada discloses a composition that comprises a crystalline drug and cellulose acetate phthalate and cellulose acetate phthalate is one of the polymers listed/recited. Therefore, the rejection is proper. It is respectfully noted that applicants on page 29 of the amendment filed 01/24/05, state that it does not matter how a composition is made and that what matters is the composition itself in a composition. Thus the process of preparing the composition by mixing is not critical in the composition. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art,

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the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Declaration and the rejections over Curatolo and Patel

The 131 declaration by Douglas A. Lorenz removes Curatolo and Patel and art since examined application is declared to be invented before Curatolo and Patel.

7. Claims 1, 30, 58, 86, 126 and 156-161 are rejected under 35 U.S.C. 102(e) as being anticipated by Bymaster et al. (US 6,147,072).

Bymaster discloses treating psychosis, acute mania, mild anxiety states or depression by administering to a patient in need thereof a composition that comprises a first component drug selected from olanzapine, clozapine, risperidone, sertindole, quetiapine and ziprasidone, and a second component (abstract; column 1, lines 42-46; column 2, line 9-51; and claim 2), and the composition is formulated as tablets, chewable tablets, capsules, solutions, intranasal sprays or powders, troches, suppositories, transdermal patches and suspensions (column 10, lines 8-12) and polymers such as hydroxypropyl methylcellulose phthalate and hydroxypropyl methylcellulose acetate succinate are associated with the drug (column 10, lines 61-67).

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 146, 147, 151-155, 162 and 163 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bymaster et al. (US 6,147,072).

Bymaster is discussed above. The difference between Bymaster and the instant claims is that Bymaster does not disclose the drug-polymer particles range in sizes of from about 10 to

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about 1000 nanometers. However, there is no demonstration that particles having sizes of from about 10 to 1000 nanometers provides unusual results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the composition of Bymaster where the drug and the polymer are associated with the expectation of delivering effective amounts of the drugs to effectively treat the targeted condition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
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